

REMARKS

Applicants request reconsideration and allowance of the subject application in view of the preceding amendments and the following remarks.

Claims 1, 2, 4, 5-7, 18 and 19 are presently pending in this application with claims 1 and 2 being independent. Claims 2 and 7 have been amended to better define and distinctly claim the scope of Applicants' invention.

The Examiner notes that the status of claim 6 is unclear, and that it is directed to a non-elected invention. As such claim was not explicitly cancelled, claim 6 is pending. Moreover, since claim 6 relates to the use of the subject matter of an elected product claim, rejoinder is appropriate upon allowance of any antecedent claim.

Applicants respectfully request that all claim amendments be entered in this application. Applicant could not have presented these amendments earlier because it was earnestly believed that the claims as heretofore presented would be deemed allowable over the cited art. Moreover, given the Examiner's familiarity with this application,

Applicants submit that full consideration of these amendments will not require undue time or effort.

Claim 7 stands rejected under 35 U.S.C. §112 as indefinite since the Examiner states it is unclear what "administering" is directed to. In response, claim 7 has been amended to recite "administering the composition according to claim 19 to a patient in need thereof". Accordingly, this rejection is now overcome.

Claims 2, 4, 5, 7, 18 and 19 stand rejected under 35 U.S.C. §112 since claim 2 is said to recite nucleotide sequences consisting of specific residues that are not described in the specification. In response, claim 2 has been amended to recite "a nucleotide sequence selected from the nucleotide sequences consisting of the open reading frames of SEQ ID NO:1-6." As the Examiner will appreciate, the nucleotide sequences comprising the open reading frames (coding regions) of SEQ ID NO:1-6 are clearly depicted in the Sequence Listing as well as being plainly described on pages 60-68 of the specification.

Claim 4 is said to recite "mRNA" which can be interpreted as drawn to essentially any mRNA. In response, Applicants would like to note that claim 4 is directed to a method for detecting mRNA using the DNA according to any one

of claims 1 or 2. Accordingly, the recited mRNA is restricted to only those mRNA that can be detected by the DNA of claims 1 or 2 rather than to any random mRNA.

Claim 7 is objected to because the Examiner states that the specification does not provide any teaching concerning treatment using the DNAs recited in claim 2 to which claim 7 depends. As claim 2 has been amended above, the objection to claim 7 is now overcome as well.

Claims 1, 2, 4, 5, 7, 18 and 19 stand rejected under 35 U.S.C. §112, first paragraph, as failing to satisfy the written description requirement for the reasons noted.

Applicants respectfully traverse this rejection. According to MPEP § 2163.02, the fundamental factual inquiry for determining compliance with the written description inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed.

First, claim 1 is essentially an original claim and therefore provides its own written description.

Moreover, in any event, Applicants identified the nucleotide sequences represented by SEQ ID NO:1-6, and 9-12 as DNAs whose expression level fluctuates in leukocytes of IgA nephropathy patients in comparison with leukocytes of

healthy persons. Given the detailed disclosure of the cloning and characterizing of these DNAs, the hybridization conditions under which a DNA which hybridizes to the isolated DNA of claim 1 (see page 6, line 16 through page 7, lines 14-20), one of ordinary skill in the art is well-aware that the invention encompasses both the isolated DNAs and DNAs which hybridize to the isolated DNAs.^{1/} Accordingly, claim 1 is directed to an isolated DNA comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:1-6 or 9-12, or a DNA which hybridizes with said DNA under specified conditions necessarily defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed.

Claim 2 as amended is directed to an isolated DNA comprising a nucleotide sequence selected from the nucleotide sequences consisting of the open reading frames of SEQ ID NO:1-6, or a DNA comprising a sequence complementary to said DNA. Claim 2 now relates to coding regions of SEQ ID NO:1-6 and complementary sequences of the coding sequences. As such, claim 2 no longer encompasses any nucleotide flanking

^{1/} As the subject matter of a claim need not be described literally in order to satisfy the written description requirement (see MPEP 2163.02), no description of the structures of DNAs which hybridize to the isolated DNAs of claim 1 is necessary.

sequence noted by the Examiner.

Claims 1, 2, 4, 5, 7, 18 and 19 also stand rejected under 35 U.S.C. §112, first paragraph, as failing to be supported by an enabling specification. More specifically, the Examiner contends that although the specification provides enablement for DNA comprising the nucleotide sequences of SEQ ID NO:1-6 and 9-12, it does not provide enablement for nucleotide sequences comprising allelic variants or flanking sequences.

First, claims no longer encompass the flanking sequences. Second, as discussed in the preceding pages, Applicants identified the nucleotide sequences represented by SEQ ID NO:1-6, and 9-12 as DNAs whose expression level fluctuates in leukocytes of IgA nephropathy patients in comparison with leukocytes of healthy persons. The specification provides a detailed description of the cloning and characterizing of these DNAs. Accordingly, the considerable direction and guidance provided by the specification would be sufficient to allow one reasonably skilled in the art to make or use the DNA which hybridizes to the isolated DNA without undue experimentation.

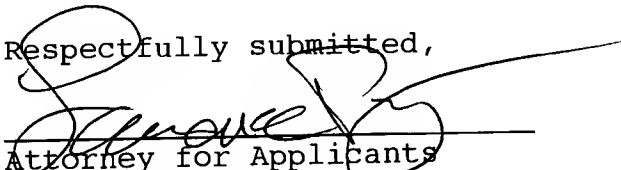
The last outstanding issue is the rejection of claims 2, 18 and 19 stand rejected under 35 U.S.C. §102 as

anticipated by Genbank Accession Number SYNPR328V. In response, claim 2 has been amended to replace "5 to 60 residues" with "10 to 60 residues". Accordingly, the noted sequences are now excluded by the amended language.^{2/}

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in condition for allowance. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our address listed below.

Respectfully submitted,


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^{2/} The probability that the claimed DNA could be identical to a known DNA sequence is only $(1/4)^{10}$.



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
TETSUYOSHI ISHIWATA et al.) : Examiner: P. Brunovskis
Application No.: 09/090,672) : Group Art Unit: 1632
Filed: June 4, 1998) :
For: IgA NEPHROPATHY-RELATED) :
GENES : April 5, 2001

APPENDIX

Claims 2 and 7 have been amended as follows.

2. (Twice Amended) An isolated DNA comprising a nucleotide sequence identical to any continuous [5] 10 to 60 residues in a nucleotide sequence selected from the nucleotide sequences consisting of [the 1st to the 1894th nucleotide of SEQ ID NO:1, the 1st to the 2644th nucleotide of SEQ ID NO:2, the 116th to the 2981st nucleotide of SEQ ID NO:3, the 1st to the 1415th nucleotide of SEQ ID NO:4, the 1st to the 2666th nucleotide of SEQ ID NO:5, the 1st to the 2244th nucleotide of SEQ ID NO:6, the 31st to the 135th nucleotide of SEQ ID NO:9, the 1st to the 93rd nucleotide of SEQ ID NO:10, the 48th to the 137th nucleotide of SEQ ID NO:11, and the 1st

to the 193rd nucleotide of SEQ ID NO:12] the open reading frames of SEQ ID NO:1-6, or

a DNA comprising a sequence complementary to said DNA.

7. (Twice Amended) A method of treating IgA nephropathy comprising administering the composition according to claim 19 to a patient in need thereof.

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